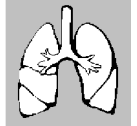




CDHS/CTCA JOINT GUIDELINES

Guidelines for the Follow-Up and Assessment of Persons with Class B1/B2 Tuberculosis



The following guidelines have been developed by the California Department of Health Services, Tuberculosis Control Branch, and the California Department of Health Services, Local Assistance Branch, Refugee Health Section in consultation with the Executive Committee of the California Tuberculosis Controllers Association. These guidelines are official State Recommendations and have been endorsed by the California Tuberculosis Controllers Association.

Background

In 1997, over one-third of foreign-born tuberculosis (TB) cases in the United States were diagnosed in California, and two-thirds of all cases in California occurred in the foreign-born population. Recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Council for the Elimination of Tuberculosis (ACET) have emphasized the screening of high-risk populations for TB, including recent immigrants from areas of the world with a high prevalence of TB. Therefore, screening of foreign-born persons is a public health priority in California.

The B notification program is an important screening strategy to identify immigrants and refugees who have a high risk for TB. The overseas screening process is intended to exclude infectious persons from entering the United States and to ensure that new arrivals who have active TB or who are at high risk for TB receive medical services. Visa applicants 15 years of age or older must have a chest radiograph (CXR) performed overseas. If the CXR is suggestive of active pulmonary TB, sputa for acid-fast bacillus (AFB) smears must be obtained. Applicants are then classified as described in the following matrix:

Immigrant/ Refugee Classification	Overseas CXR	Overseas Sputum AFB Smears	Restrictions
A Waiver *	Abnormal, suggestive of active TB	Positive	May not enter the U.S. until started on anti-TB therapy and sputum smears are negative and: 1) Apply for a waiver signed by the local health department in their intended U.S. destination (A waiver), or 2) Complete TB therapy overseas
B1	Abnormal, suggestive of active TB	Negative	Instructed to report to the local health department in the US for further medical evaluation within 30 days of arrival
B2	Abnormal, suggestive of inactive TB	Not done	Same as above

* Very few persons with A waivers enter California, so they are excluded from these recommendations.

When a person with Class B1/B2 TB moves to the United States, the Centers for Disease Control and Prevention, Division of Quarantine notifies the local health jurisdiction (LHJ) in the individual's intended county of residence that medical follow-up is necessary. The person is instructed to report to the LHJ within one month of arrival. LHJs should make follow-up of persons with B notification as high a public health priority as is contact investigation. A California Department of Health Services' analysis of persons with B notification entering the United States between January 1992 and September 1995 found that 4% were reported to have TB disease within one year of arrival. In terms of the number of cases detected, the yield of B notification follow-up (40 cases per 1000 immigrants evaluated) exceeds that of contact investigation (10 cases per 1000 contacts evaluated). B notification follow-up also provides LHJs an important means to prevent future cases since approximately 40% of persons evaluated have inactive TB (TB4) or TB infection (TB2) for which treatment is indicated (2, 5, 8).

B Notification Project

To better understand B notification practices and challenges in California, the California Department of Health Services, Tuberculosis Control Branch (CDHS/TBCB) surveyed local TB control programs that receive local assistance allocations in early 1997 and local refugee health programs in early 1998. We asked about their process for tracking and follow-up of persons with B notifications and the barriers encountered. We then reviewed the B notification systems in several TB control and refugee health programs in California and other states to identify successful methods (i.e. "best practices") for ensuring the early identification and evaluation of such individuals.

The recommendations that resulted from this process emphasize:

- C Methods for ensuring that LHJs perform timely and complete TB evaluations of immigrants and refugees arriving with B notifications;
- C Initiating and completing chemotherapy for those with active TB;
- C Initiating and completing treatment for medically eligible persons with inactive TB or TB infection; and
- C Evaluating the effectiveness of B notification activities.

B Notification Goal

All newly arrived refugees and immigrants with Class B1/B2 TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.

B Notification Objectives

LHJs should set realistic local objectives for the following indices and measure program performance against these established targets on at least an annual basis (see **Attachment 1** for recommended objectives):

- I. At least ____% of persons entering the jurisdiction with Class B1/B2 TB will receive an initial evaluation for TB disease/infection within one month of receipt of B notification.
- II. At least ____% of persons with Class B1/B2 TB who are diagnosed with active TB disease will be placed on multidrug therapy
- III. At least ____% of persons entering the jurisdiction with Class B1/B2 TB who have inactive disease (TB4) and who are eligible for treatment of latent infection will start treatment.

- IV. At least ____% of persons entering the jurisdiction with Class B1/B2 TB who have inactive disease (TB4) and who initiate treatment of latent infection will complete it.
- V. At least ____% of persons entering the jurisdiction with Class B1/B2 TB who are infected without disease (TB2) and who are eligible for treatment of latent infection will start treatment.
- VI. At least ____% of persons entering the jurisdiction with Class B1/B2 TB who are infected without disease (TB2) and who initiate treatment of latent infection will complete it.

Recommendations for Follow-Up and Assessment of Persons with Class B1/B2 Tuberculosis

- I. Receiving and logging B notifications
 - A. Counties may receive B notifications from a variety of sources including the following:
 - 1. Division of Quarantine (DOQ) slips from the Ports of Entry
 - 2. Transfers from other jurisdictions and states
 - 3. Immigrants/refugees who walk-in for evaluation without prior notice of B notification
 - 4. Proposed electronic B notification files
 - B. Local health jurisdictions (LHJs) should establish a mechanism to effectively log, track, and evaluate B notification follow-up. To accomplish this, it is generally helpful to receive and process B notifications in a central coordinating location. Larger LHJs may find it helpful to designate one person such as a Class B1/B2 clerk to be the central contact person concerning B1/B2 inquiries. In counties where there is a separate refugee program, it may act as a separate collection and coordinating point for refugee B notifications if more convenient.
 - C. All LHJs should evaluate their performance in meeting B notification objectives. To accomplish this, LHJ staff may want to record all B notifications received in a registry or log. Documentation should reflect information that will be evaluated or otherwise meets local needs and may include the following information:
 - 1. Date notification received
 - 2. Date person arrived in the U.S.
 - 3. Name/age/country of origin/address/telephone number
 - 4. Alien number - The DOQ Immigration and Naturalization Services alien number
 - 5. Type of notification (B1 or B2)
 - 6. Date of initial medical evaluation in the U.S.
 - 7. Number of days from arrival date to date of initial evaluation

8. Initial Disposition:
 - a. TB classification (0, 1, 2, 3, 4, 5)
 - b. Moved prior to initial evaluation (include forwarding address)
 - c. Lost/refused/unable to locate
 - d. Died
 - e. Other
9. If TB2 or TB4, is patient a candidate for treatment? Yes or no.
10. Final Disposition:
 - a. TB classification (0, 1, 2, 3, 4, 5)
 - b. Moved prior to initial evaluation (include forwarding address)
 - c. Lost/refused/unable to locate
 - d. Died
 - e. Other
11. Therapy start and end dates (for TB3s and TB5s only) and disposition (completed, TB ruled-out, lost/refused, died, d/c due to toxicity, other)
12. Preventive therapy start and end dates (for TB2s and TB4s only) and disposition (completed, moved, lost/refused, died, d/c due to toxicity, other)
13. Comments

II. Ensuring rapid notification and follow-up of persons with B notifications

- A. Due to the mobility of many newly arrived immigrants and refugees, LHJ staff should attempt to locate and evaluate individuals as soon as possible following their arrival. Also, efforts to locate and evaluate individuals with B notifications quickly are likely to be more cost effective than treating them and conducting more extensive contact investigations if they are later discovered to have disease. LHJ staff should initiate follow-up within two weeks of receipt of the B notification.
- B. Because persons with B1 notifications are more likely to have active TB than persons with B2 notifications, B1 notifications should be appropriately prioritized to assure prompt and proactive follow-up.
- C. Recommended activities for locating persons with B notifications are as follows:
 1. TB control and refugee health programs should use a variety of active outreach strategies to locate persons with B notifications, including letters, telephone calls, and home visits.

2. Outreach strategies should consider the language and cultural needs of newly arrived persons. For example, whenever possible, public health staff who speak the person's primary language should telephone the new arrival. (**Note:** the CDC 75.17 Form usually specifies the person's country of origin). Any correspondence should ideally be written in English and the patient's primary language. Public health staff who do not speak the patient's language should be teamed with a trained and culturally sensitive interpreter when performing home visits. Effective communication can promote greater patient trust and improve evaluation and treatment outcomes.
3. If the person has moved, obtain new locating information (e.g., home address and telephone number, place of employment). LHJ staff may obtain this information from a variety of sources, including the person's sponsor, family members, the local post office, community-based organization, or Voluntary Agencies. Forward this information and the CDC 75.17 Form to the receiving LHJ.
4. If the person has already returned to his/her country, ask sponsor/family/friends to notify LHJ staff if the person returns. In some LHJs, staff will periodically (e.g., monthly for six months) call or visit the person's family or friends to determine if (s)he has returned.
5. LHJ staff should use incentives (e.g., grocery vouchers, etc.), enablers (e.g. bus tokens, etc.), and other adherence enhancing interventions (e.g., bilingual/bicultural staff) to improve adherence with B notification follow-up.
6. If the individual cannot be located or fails to make contact with the health department within five days following a home visit or refuses examination, the LHJ should consider requesting, where available, the assistance of local or state disease intervention specialists, Voluntary Agencies, and community-based organizations. LHJs may also consider using legal orders. If these strategies fail, document efforts and consider closing as "unable to locate" or "refused examination."

III. Ensuring adequate and complete TB evaluation and treatment of persons with B notification

The primary purpose of the following evaluation is to ensure that all active TB cases are identified. However, a secondary purpose is to identify persons with TB infection (but not active TB) who are eligible for a course of treatment for TB infection. Therefore, the evaluation of persons with B notification is only complete when they have been evaluated for their eligibility to receive treatment for TB disease and infection.

- A. In-person evaluation of all individuals with B notification is labor and resource intensive. However, this is important to ensure complete evaluation of these persons and includes the following:
 1. Review the overseas CXR to determine if there is evidence of TB disease. Repeat the CXR if any of the following is present:
 - a. Overseas CXR is technically inadequate or not available for review, or
 - b. Suspicion for TB is high enough that the patient is being started on treatment for suspected active TB disease (repeat CXR regardless of when the overseas CXR was obtained), or

- c. Abnormalities on the overseas CXR meet radiographic criteria for active or inactive TB (i.e. TB5 or TB4*) AND the CXR was taken more than three to six months ago.
2. Interview the patient to obtain information on medical history. This includes history of known exposure to TB, prior TB diagnosis or treatment, prior tuberculin skin test (TST) results, and any indications or contraindications to a course of treatment for TB infection (See CDHS/CTCA “Guidelines for the Treatment of Tuberculosis and Tuberculosis Infection in California”).
3. Health departments have the option to perform a Mantoux TST in all persons with B notification. At the very least, a TST should be performed on the following individuals with B notification:
 - a. Persons under age 35, or
 - b. Persons with CXR meeting radiographic criteria for active or inactive TB (i.e. TB5 or TB4*), or
 - c. Persons with medical risk factors known to increase the progression from TB infection to disease (See CDHS/CTCA “Guidelines for the Treatment of Tuberculosis and Tuberculosis Infection in California”).

There is no consensus on the use of two-step testing to evaluate for TB infection in persons whose delayed-type hypersensitivity to tuberculin may wane over the years and result in false-negative TST reaction. Waning of delayed-type hypersensitivity is more common in persons >50 years old. Health departments choosing to use two-step testing to identify TST-positive individuals should be aware of the potential problems with boosting because of exposure to non-tuberculous mycobacteria, including exposure from BCG vaccination.

4. Sputum should be collected for sputum microscopy and mycobacterial culture whenever there is a suspicion of active TB disease.
 - a. Obtain sputum on three consecutive days from patients who have abnormalities on the CXR obtained overseas or in the U.S. that meet radiographic criteria for inactive or active TB (i.e. TB4* or TB5); sputum collection is recommended even when the CXR abnormalities appear stable.
 - b. If the patient cannot produce sputum spontaneously, perform sputum induction.

* Additional information about radiographic findings for TB4 classification:

1. An example of CXR finding meeting radiographic criteria for inactive TB (i.e. TB4) is fibronodular opacities.
2. Examples of CXR findings that by themselves alone should not result in a TB4 classification (unless the person has a history of TB) include but are not limited to:
 - C Solitary calcified lesion
 - C Thickening of apical or diaphragmatic pleura
 - C Hilar calcification

B. Treatment decisions

Please refer to the CDHS/CTCA “Guidelines for the Treatment of Tuberculosis and Tuberculosis Infection in California” for treatment information. Also see CDHS/CTCA “Directly Observed Therapy Program Protocols in California,” and CDHS/CTCA “TB Case Management - Core Components.”

C. Private Sector Care Issues

1. Whenever possible, LHJs should encourage persons with B notifications to be clinically evaluated in LHJ TB or refugee health clinics. When patients are evaluated in the private sector, the LHJ remains responsible for ensuring their complete and adequate evaluation and treatment.
2. Refer to the CDHS/CTCA “Guidelines for Oversight of Tuberculosis Care Provided Outside the Local Health Department Tuberculosis Program,” for additional information.
3. State regulations require health care providers to report TB to the LHJ in which the patient resides within one working day of identification of the case or suspected case. See CDHS/CTCA “Guidelines for Reporting Tuberculosis Suspects and Cases in California,” for additional information.

NOTE: No set of guidelines can cover all individual Class B1/B2 TB follow-up and assessment issues which can and will arise. Thus, when questions on individual situations not covered by these guidelines do arise, consult with the Local TB Control Program or the California Department of Health Services, TB Control Branch, for consultation and further information.

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Recommended B Notification Program Performance Objectives

As noted in the CDHS/CTCA “Guidelines for the Follow-Up and Assessment of Persons with Class B1/B2 Tuberculosis,” local health jurisdictions should set realistic local objectives for B notification follow-up and measure program performance against these established targets on at least an annual basis. Recommended objectives, which may be achievable with an ideal follow-up mechanism and adequate resources, are as follows:

- I. At least **80%** of persons entering the jurisdiction with Class B1/B2 TB will receive an initial evaluation for TB disease/infection within one month of receipt of B notification.
- II. **100%** of persons with Class B1/B2 TB who are diagnosed with active TB disease will be placed on multidrug therapy
- III. At least **90%** of persons entering the jurisdiction with Class B1/B2 TB who have inactive disease (TB4) and who are eligible for treatment of latent infection will start treatment.
- IV. At least **75%** of persons entering the jurisdiction with Class B1/B2 TB who have inactive disease (TB4) and who initiate treatment of latent infection will complete it.
- V. At least **80%** of persons entering the jurisdiction with Class B1/B2 TB who are infected without disease (TB2) and who are eligible for treatment of latent infection will start treatment.
- VI. At least **75%** of persons entering the jurisdiction with Class B1/B2 TB who are infected without disease (TB2) and who initiate treatment of latent infection will complete it.